K05 3455

Empiric™ Systems

JAN 25 2006

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

November 30, 2005

Submitter's Information: 21 CFR 807.92(a)(1)

Mark Janas
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1800 Perimeter Park Dr., Suite 120
Morrisville, NC 27560
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	Encompass.Net™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 System, Image Processing
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number	K022970
Regulation Number	892.2050
Device Name	Amicas Light Beam Workstation
Applicant	Arnicas Inc.
Classification Product Code	LLZ
Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL

Device Description: 21 CFR 807 92(a)(4)

Encompass.Net™ is a fully web-based system that operates in a Microsoft Internet Explorer (Version 6.0 and above) environment. Encompass.Net™ is run in a Windows 2003 environment, using Microsoft's Internet Information Server functions. The core database is Microsoft SQL 2000.

Encompass.Net is intended to acquire medical images for storage, archiving, and routing to medical professionals. In addition, Encompass.Net allows medical professionals to retrieve medical images on demand using Internet communication protocols according to various user options and lossy and/or lossless compression techniques for subsequent review. A host of image process tools are available for the medical professional.

In addition to Encompass.Net, the fully integrated RIS/PACS device, there are also multiple stand-alone PACS models (subsets of Encompass.Net) that will be marketed. Those configurations are: R1.Net, R2.Net, and R3.Net.

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Indications for Use: 21 CFR 807 92(a)(5)

Encompass.Net™ device is software intended for viewing and diagnostic interpretation of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Encompass.Net™ receives imaging studies over a network from Empiric Systems servers or directly from CD with images utilizing both lossless (reversible) and lossy (irreversible) compression. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with clinical application.

Technological Characteristics: 21 CFR 807 92(a)(6)

Encompass.Net™ device is a software product that handles digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510 (k) Pre-Market Notification for Encompass.Net™ device contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

Encompass.Net™ device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2006

Empiric Systems, LLC
% Mr. Carl Alletto
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K053455
Trade/Device Name: Encompass.Net™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 18, 2005
Received: December 9, 2005

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K053455

Device Name:
Encompass.Net™

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053455